Docket No.: 200773US0DIV

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Pierre DRUILHE et al. : ATTN: APPLICATION DIVISION

SERIAL NO: NEW APPLICATION :

FILED: HEREWITH :

FOR: MALARIAL PRE-ERYTHROCYTIC STAGE POLYPEPTIDE MOLECULES

PRELIMINARY AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Prior to examination on the merits, please amend the above-identified application as follows.

IN THE SPECIFICATION

Please amend the specification as follows:

Page 1, before line 1, please insert

--This application is a Divisional of U.S. Application Serial No. 08/973,642, filed on February 6, 1998, now allowed, which is a 371 of PCT/FR96/00894, filed June 12, 1996.--

Please delete the original Sequence Listing at page 36.

Page 41 (Abstract), after the last line, beginning on a new page, please insert the attached substitute Sequence Listing.

IN THE CLAIMS

Please cancel Claims 1-26.

Please add the following claims.

--27. A polypeptide molecule containing at least 10 consecutive amino acids of the amino acid sequence shown in Figure 2 (SEQ ID NO:2),

with the proviso that the following polypeptides are excluded:

(i) RDELFNELLNSVDVNGEVKENILEESQVNDDIFNSLVKSVQQEQQHNV EE (SEQ ID NO: 10),

(ii) VEESVEENDEESVEENVEENVENNDDGSVASSVEESIASSVDESIDSSIE ENVAPTVEEIVAPTVEEIVAPSVVEKCAPSVEESVAPSVEESVAEMLKE R (729S, SEQ ID NO: 11),

(iii) RDELFNELLNSVDVNGEVKENILEESQVNDDIFNSLVKSVQQEQQHN (SEQ ID NO: 12),

(iv) DELFNELLNSVDVNGEVKENILEESQ (NRI, SEQ ID NO: 13),

(v) LEESQVNDDIFSNSLVKSVQQEQQHNV (NRII, SEQ ID NO: 14), and

(vi) VESVAPSVEESVAPSVEESVAENVESSV (729RE, SEQ ID NO: 15).

28. The polypeptide molecule of Claim 27, containing at least 20 consecutive amino acids of the said sequence.

29. The polypeptide molecule of Claim 27, containing at least 50 consecutive amino acids of the said sequence.

30. A polypeptide molecule displaying at least 70% homology with the polypeptide molecule of Claim 27.

31. A polypeptide molecule displaying at least 70% homology with the following sequence:

Leu Leu Ser Asn Ile Glu Glu Pro Lys Glu Asn Ile Ile Asp Asn Leu Leu Asn Asn Ile (CT1).

32. The polypeptide molecule according to Claim 27, displaying at least 70% homology with the sequence depicted in Figure 3 (SEQ ID NO: 3).

33. A method of *in vitro* diagnosis of malaria in an individual likely to be infected by *P. falciparum*, which comprises the bringing of a tissue or biological fluid taken from an individual into contact with a polypeptide molecule according to Claim 27, under conditions permitting an immunological reaction between the said polypeptide molecule and the antibodies possibly present in the tissue or the biological fluid, and the *in vitro* detection of the antigen/antibody complexes possibly formed.

34. The method of Claim 33, characterized in that the tissue or biological fluid is brought into contact with a mixture of said polypeptide molecules and other molecules originating from antigens of the sporozoite stage, namely LSA-1, SALSA or STARP.

35. A kit for the *in vitro* diagnosis of malaria, characterized in that it comprises at least one polypeptide molecules according to Claim 27, the reagents for making up the appropriate medium for the reaction, the reagents enabling the antigen/antibody complexes produced by the immunological reaction to be detected, it also being possible for these reagents to carry a label or to be capable of being recognized in their turn by a labeled reagent, more especially in the case where the above-mentioned polypeptide molecule is not labeled.

36. A kit for the *in vitro* diagnosis of malaria, characterized in that it comprises at least one polypeptide molecules according to Claim 30, the reagents for making up the appropriate medium for the reaction, the reagents enabling the antigen/antibody complexes produced by the immunological reaction to be detected, it also being possible for these reagents to carry a label or to be capable of being recognized in their turn by a labeled reagent, more especially in the case where the above-mentioned polypeptide molecule is not labeled.

37. A kit for the *in vitro* diagnosis of malaria, characterized in that it comprises at least one polypeptide molecules according to Claim 31, the reagents for making up the appropriate medium for the reaction, the reagents enabling the antigen/antibody complexes produced by the immunological reaction to be detected, it also being possible for these reagents to carry a label or to be capable of being recognized in their turn by a labeled reagent, more especially in the case where the above-mentioned polypeptide molecule is not labeled.

38. A kit for the *in vitro* diagnosis of malaria, characterized in that it comprises at least one polypeptide molecules according to Claim 32, the reagents for making up the appropriate medium for the reaction, the reagents enabling the antigen/antibody complexes produced by the immunological reaction to be detected, it also being possible for these reagents to carry a label or to be capable of being recognized in their turn by a labeled reagent, more especially in the case where the above-mentioned polypeptide molecule is not labeled.

39. A conjugate consisting of a polypeptide molecule according to Claim 27 and a support on which the said molecule is adsorbed.

40. A conjugate consisting of a polypeptide molecule according to Claim 30 and a support on which the said molecule is adsorbed.

41. A conjugate consisting of a polypeptide molecule according to Claim 31 and a support on which the said molecule is adsorbed.

42. A conjugate consisting of a polypeptide molecule according to Claim 32 and a support on which the said molecule is adsorbed.

43. A conjugate consisting of a polypeptide molecule according to Claim 33 and a support on which the said molecule is adsorbed.

44. The conjugate of Claim 39, wherein the support consists of latex or polystyrene microspheres or beads.

45. The conjugate of Claim 40, wherein the support consists of latex or polystyrene microspheres or beads.

46. The conjugate of Claim 41, wherein the support consists of latex or polystyrene microspheres or beads.

47. The conjugate of Claim 42, wherein the support consists of latex or polystyrene microspheres or beads.

48. The conjugate of Claim 43, wherein the support consists of latex or polystyrene microspheres or beads.

49. An isolated nucleic acid, containing a sequence coding for a polypeptide molecule containing at least 10 consecutive amino acids of the amino acid sequence shown in Figure 2 (SEQ ID NO: 2), with the proviso that the following polypeptides are excluded:

(i) RDELFNELLNSVDVNGEVKENILEESQVNDDIFNSLVKSVQQEQQHNV EE (SEQ ID NO: 10),

(ii) VEESVEENDEESVEENVEENVENNDDGSVASSVEESIASSVDESIDSSIE ENVAPTVEEIVAPTVEEIVAPSVVEKCAPSVEESVAPSVEESVAEMLKE R (729S, SEQ ID NO: 11),

(iii) RDELFNELLNSVDVNGEVKENILEESQVNDDIFNSLVKSVQQEQQHN (SEQ ID NO: 12),

(iv) DELFNELLNSVDVNGEVKENILEESQ (NRI, SEQ ID NO: 13),

(v) LEESQVNDDIFSNSLVKSVQQEQQHNV (NRII, SEQ ID NO: 14), and

(vi) VESVAPSVEESVAPSVEESVAENVESSV (729RE, SEQ ID NO: 15).

50. A recombinant vector containing the nucleic acid of Claim 49.

51. The vector of Claim 50, which is a plasmid, cosmid, or phage.

52. A recombinant vector suitable for expression of a polypeptide encoded by the nucleic acid of Claim 49, containing a nucleic acid in a region which is not essential for the replication of the vector, wherein the vector is selected from the group consisting of plasmids, cosmids, and phages.

53. A method of producing an immunogenic poypeptide, comprising administering the nucleic acid of Claim 49 to a host cell, wherein the host cell produces an immunogenic polypeptide encoded by the nucleic acid.

54. A method of producing an immunogenic polypeptide, comprising administering the vector of Claim 50 to a host cell, wherein the host cell produces an immunogenic polypeptide encoded by the vector.--

REMARKS

Claims 27-54 are active in this application.

The present application is a Divisional of U.S. Application Serial No. 08/973,642, filed on February 6, 1998, now allowed, which is a 371 of PCT/FR96/00894, filed June 12, 1996.

Newly added Claims 27-54 are supported by the specification at pages 5-36 and by original Claims 1-26.

A substitute Sequence Listing is attached. In lieu of a CRF, the PTO is requested to use the CRF that was submitted in parent application Serial No. 08/973,642 on October 25, 1999. Applicants confirm that the sequence information contained in the substitute Sequence Listing attached herewith is the same as the CRF submitted in parent application.

No new matter is believed to have been added to this application by these amendments.

Applicants submit that the present application is ready for examination on the merits.

Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

James J. Kelly, Ph.D.
Registration No. 41,504

22850
(703) 413-3000
Fax #: (703) 413-2220
I:\atty\JK\200773US0.AMD.wpd